IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

SHIRLEY J. BRINKLEY	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.: 10-0274-CV-W-SOW
	)	
PFIZER, INC., et al.,	)	
	)	
Defendants.	)	

ORDER

Before the Court is defendant Pliva, Inc.'s Motion for Judgment on the Pleadings (Doc. #63). For the following reasons, the motion is hereby granted.

I. Background

In this product liability case, plaintiff Shirley Brinkley alleges that she sustained serious injuries after ingesting Reglan®/metoclopramide. Specifically, plaintiff alleges that she began taking metoclopramide between February 2002 and April 2007 and that she developed tardive dyskinesia and/or other neurological injuries after ingesting this drug. As a result, plaintiff brought claims against Pfizer, Inc., Wyeth, LLC, Schwarz Pharma, Inc., and Pliva Inc., on March 25, 2010. Pliva is the generic manufacturer of metoclopramide, a generic form of Reglan®.

On April 8, 2011, the Court stayed these proceedings because the Supreme Court of the United States granted certiorari to a collection of lawsuits dealing with the same fact pattern as this case. On June 23, 2011, the Supreme Court decided the collection of lawsuits in Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011). Following the Supreme Court's ruling in Mensing, the Court granted plaintiff leave to file an Amended Complaint in response to Mensing. On August 30, 2011, plaintiff filed her First Amended Complaint, asserting Missouri state-law claims for strict liability

(design defect) against Pliva, strict liability (failure to warn) against Pliva, negligence against all defendants, breach of express and implied warranty against Pliva, and violations of the Missouri Merchandising Practices Act ("MMPA") against Pliva. Pliva has filed a motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c), arguing that plaintiff's state law claims are preempted by federal law as held in Mensing.

II. Standard

Federal Rule of Civil Procedure 12(c) allows a party to move for judgment on the pleadings after responsive pleadings have been filed. In analyzing a motion filed pursuant to Federal Rule of Civil Procedure 12(c), the Court applies the same standard as applied when addressing a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. Westcott v. City of Omaha, 901 F.2d 1486, 1488 (8th Cir. 1990)(citing Morgan v. Church's Fried Chicken, 829 F.2d 10, 11 (6th Cir. 1987)). The Court must assume that all factual allegations in the Complaint are true and must construe those allegations in favor of the plaintiff. Klutho v. New Day Fin., LLC, 522 F. Supp. 2d 1174, 1176 (E.D. Mo. 2007).

"Judgment on the pleadings is appropriate where no material issue of fact remains to be resolved and the movant is entitled to judgment as a matter of law." Faibisch v. Univ. of Minn., 304 F.3d 797, 803 (8th Cir. 2002).

III. Discussion

Pliva argues that the Supreme Court's decision in Mensing preempts plaintiff's state law claims and, therefore, the Court should dismiss the claims against it. The plaintiffs in Mensing claimed that the state tort laws in Minnesota and Louisiana required a manufacturer that is, or should be, aware of its drug's danger to label it in a way that renders it reasonably safe. Thus, the plaintiffs

in Mensing claimed that the manufacturers knew, or should have known, that the long-term usage of metoclopramide resulted in tardive dyskinesia and that their labels did not adequately warn users under the respective state laws. If this were true, the state law duty would have required the manufacturers to use a different, stronger label than the one that was used.

Over the years, the labels for metoclopramide have been revised, strengthened, and clarified a number of times. Mensing, 131 S. Ct. at 2572. In 1985, the label was modified to warn that "tardive dyskinesia may develop in patients treated with metoclopramide," and the drug's package insert added "that [t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Id. In 2004, Reglan® requested, and the FDA approved, a label change to include that "[t]herapy should not exceed 12 weeks in duration." Id. Its strongest warning came in 2009, when the FDA ordered a black box warning: "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." Id. at 2573. Nonetheless, the plaintiffs argued that the warnings were inadequate. The manufacturers responded that federal statutes and the Federal Drug Administration ("FDA") regulations required them to use the same safety and efficacy labeling as brand-name manufacturers.

The Supreme Court ultimately decided that federal drug regulations preempted state law failure to warn claims against generic drug manufacturers. Id. at 2572. The question presented was whether individuals injured by generic drugs they claimed had inadequate warning labels could sue the manufacturers of such generic drugs for damages under state law, or whether the FDA regulations for drug labeling preempted these types of suits. Id. In the end, the Court ruled 5-4 that the generic manufacturers could not be sued because it was impossible for them to comply with both

federal law and state law.

The Supreme Court noted that the federal regulations, as promulgated by the FDA, imposed a more complex labeling requirement than state tort law did. Id. at 2754. This conflict between the complex FDA requirement and the state law requirement led the Court to conclude that impossibility preemption existed because it was impossible for the generic manufacturers to comply with both state law and federal law. Id. at 2579. The Court also pointed out that "[t]he only action the [generic] manufacturers could independently take – asking for the FDA's help – is not a matter of state law concern. Id. at 2581.

The practical effects of this decision leave generic drug manufacturers immune from suit under state tort law for failure to warn. Indeed, "[h]ad Mensing and Demahy taken Reglan®, the brand-name drug prescribed by their doctors, Wyeth would control and their law suits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits . . . We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, *and others similarly situated*." Id. at 2582 (emphasis added). Justice Sotomayor, acknowledging the impact the majority's decision would have, started her dissenting opinion by stating, "[t]oday's decision affects 75 percent of all prescription drugs dispensed in this country." Id. at 2583.

As relevant to this motion, plaintiff's Amended Complaint alleges:

- Pliva manufactured, marketed, labeled, and sold Reglan®/metoclopramide to plaintiff which did not have the same label content as its name-brand Reglan® counterpart and, in particular, never included the February 2004 revision, approved by the FDA in July 2004, which contained additional language indicating that "[T]herapy should not exceed 12 weeks in duration."

- Pliva failed to communicate, publish, or disseminate accurate product labeling or warning information for its Reglan®/metoclopramide to anyone in the medical

community, including pharmacies and distributors, as well as plaintiff, plaintiff's physician, and other foreseeable users of metoclopramide.

- Under the ANDA process, the Code of Federal Regulations required generic drug manufacturers such as Pliva, that were involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCI, to submit labels for Reglan®/metoclopramide that were identical in all material aspects to the reference listed drug label.

- Under the Code of Federal Regulations, Pliva had a duty to ensure its Reglan®/metoclopramide warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by metoclopramide.

- Under the Code of Federal Regulations, if Pliva discovers information in the course of fulfillment of its duties, it must report that information to the FDA in order to ensure that warnings for Reglan®/metoclopramide are accurate and adequate.

- Pliva failed to adequately investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug labels.

- Pliva failed to review the available medical literature applicable to the metoclopramide drug and/or metoclopramide HCl drug.

- Plaintiff relied entirely upon the name brand manufacturer and the reference listed drug companies to review the aforementioned medical literature for Reglan®/metoclopramide and to disseminate FDA approved product labeling to prescribing physicians.

- Pliva was not required by federal law to sell Reglan®/metoclopramide and if, at any time Pliva knew or should have known its Reglan®/metoclopramide posed an unreasonable risk of harm to patients, it could have made a unilateral decision to stop marketing and selling Reglan®/metoclopramide. If a generic manufacturer understands that compliance with federal law may require selling a drug with inadequate label content, that manufacturer has a choice between two options: (a) continue selling the drug with the same label content as the name-brand; or (b) stop selling the drug unilaterally because it knows know, in its current form, it is causing catastrophic injuries.

- Pliva could have unilaterally sent a copy of its FDA approved product label for Reglan®/metoclopramide to plaintiff's prescribing physician(s) as long as the Pliva label contained the same content as the RLD labeling for Reglan®.

- Pliva knew or should have known that defendant Schwarz had not published the Reglan® label in the PDR and did not send a DHCP letter to inform physicians about the 2004 label revision.

- Between February 2004 and April 2007, Pliva had a state law obligation to ensure that plaintiff's prescribing physician was aware of the July 2004 label change applicable to Reglan®/metoclopramide and had appropriate knowledge of the updated FDA approved product label.

- Between February 2004 and April 2007, Pliva breached its obligation to ensure that plaintiff's prescribing physician was aware of the July 2004 Reglan®-/metoclopramide label change and had appropriate knowledge of the updated FDA approved product label.

- Pliva knew or should have known that it was unreasonable to believe that prescribing physicians, including plaintiff's physician, would become aware of the 2004 Reglan®/metoclopramide label revision, which only appeared on the FDA website, where defendants and other manufacturers of metoclopramide never published, disseminated, or provided the updated package insert or product label to prescribing physicians.

- Pliva failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan®/metoclopramide.

- Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Reglan®/metoclopramide substantially understated the prevalence of acute and long-term side effects of ingesting the drug.

- Defendants failed to conduct and report post market safety surveillance on Reglan®/metoclopramide.

- Defendants failed to monitor all relevant scientific literature related to Reglan®/metoclopramide.

- Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan®/metoclopramide for long periods of time.

- Defendants failed to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Reglan®/metoclopramide.

- Defendants knowingly concealed from physicians material facts bearing on the

interpretation of package insert disclosures that exposure to Reglan®/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and the therapy for longer than 12 weeks "cannot be recommended."

- Pliva knowingly or negligently concealed from physicians the Reglan®/metoclopramide approved product labeling and all warning information contained therein.

- Upon information and belief, despite having clear notice of defendants Wyeth and Schwarz's tortious conduct as described above, defendant Pliva failed to update its Reglan®/metoclopramide label to match the RLD label while plaintiff was being exposed to Pliva metoclopramide.

- Upon information and belief, at relevant times, defendant Pliva sold its Reglan®/metoclopramide to plaintiff with product labeling that contained substantially less information and content relating to appropriate duration of use when compared to other manufacturers of Reglan®/metoclopramide.

- Upon information and belief, and at relevant times, because defendant Pliva's Reglan®/metoclopramide label was not the same as the RLD label and lacked additional language that was added in the 2004 revised Reglan® label, defendant Pliva was negligent and breached its state law duty to effectively communicate a warning to plaintiff's prescribing physician regarding appropriate duration of Reglan®/metoclopramide usage.

In response to Pliva's motion for judgment on the pleadings, plaintiff claims that this case is different from Mensing for a variety of reasons. First, the "Court in Mensing did not consider all possible causes of action arising under state law but, in fact, narrowly focused its ruling upon those presented, leaving plaintiff's existing claims wholly unaddressed." Second, other courts, including the Court overseeing the consolidated Reglan®/metoclopramide litigation in Philadelphia, Pennsylvania, have refused to grant blanket dismissals because of Mensing. Third, this case is different than Mensing because plaintiff is not trying to impose liability under state law for warnings that Pliva could not change. "Instead, plaintiff seeks to impose liability against Pliva for failing to communicate existing FDA approved label content for its metoclopramide to plaintiff's prescribing

physician during a time frame that involved" several unique events and circumstances. Fourth, because plaintiff alleges Pliva engaged in numerous activities that were prohibited by federal law, these claims are not preempted. Lastly, because plaintiff is not trying to impose liability on Pliva for failing to change its metoclopramide label in a manner that would be inconsistent or contrary to the FDA approved label for brand-name Reglan®, her claims do not conflict with Mensing.

Plaintiff argues that the issue before the Supreme Court in Mensing was whether it was possible for a generic drug manufacturer to unilaterally change its labeling to add or strengthen warnings to differ from those of the Reference Listed Drug. According to plaintiff, the Mensing decision only applies to allegations that a generic manufacturer should have unilaterally changed the contents of its label. Thus, plaintiff claims that Pliva's broad reading of Mensing is incorrect. The Court disagrees with plaintiff's interpretation of Mensing.

The Supreme Court's decision in Mensing has affected approximately 75 percent of the prescription drug-users in this country. The Supreme Court was clear about this. While plaintiff tries to save her claims by claiming Pliva failed to communicate or disseminate accurate information to patients and physicians, among other things, the Court fails to see how these allegations differ from those in Mensing. It is readily apparent that plaintiff is simply trying to backdoor claims against Pliva that the Supreme Court have found to be preempted. For example, plaintiff says that Pliva failed to communicate FDA warnings to plaintiff's physician(s). First, there is no state law requiring Pliva to communicate such a warning. Second, this claim appears to be nothing more than a failure to warn claim, which is preempted by Mensing. At its core, plaintiff's arguments hinge on one simple fact: Pliva failed to warn the plaintiff about the risks associated with the use of Reglan®/metoclopramide. Whether the Supreme Court was right or wrong in Mensing, the Supreme

Court has affirmatively stated that these claims are preempted, and this Court has no choice but to dismiss plaintiff's claims against Pliva with prejudice.

III. Conclusion

Accordingly, it is hereby

ORDERED that defendant Pliva, Inc.'s Motion for Judgment on the Pleadings (Doc. #63) is granted.

/s/ Scott O. Wright
SCOTT O. WRIGHT
Senior United States District Judge

DATED: April 12, 2012